Dräger medical
A Dräger and Siemens Company

K092999

510(k) Summary acc. to 21 CFR 807.92

Applicants Name and Address:

Dräger Medical AG & Co. KG
Moislinger Allee 53-55
23542 Lübeck
Germany

NOV 24 2009

Manufacturer Name and Address:

Dräger Medical AG & Co. KG
Moislinger Allee 53-55
23542 Lübeck
Germany

Establishment Registration Number :

9611500

Contact Person:

Ulrich Schröder
Director Regulatory Affairs & Clinical Affairs

Tel. No.: 011 49 (451) 882-3648
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Applicants US Contact Person

Joyce Kilroy
Vice President, Processes, Quality & Regulatory

Tel. No.: (215) 660-2626
Fax No.: (215) 721-5424

Date submission was prepared:

2009/09/25

Device Name:

Common Name:	**NBP Cuff / NBP Cuff, Neo**
Classification Name:	blood pressure cuff, DXQ
Regulation Number:	21 CFR 870.1120
Class:	II

Legally Marketed Devices to which Substantial Equivalence is claimed:

510(k) number	Trade name	Company
K022889	Siemens Infinity Modular Monitors, Models SC 8000, SC 7000 & SC 9000XL & Siemens Infinity Explorer (cuffs from supplier Statcorp)	Dräger Medical System, Inc (former Siemens Medical Solutions USA, Inc.)
K022482	Sensa-Cuf	GE Medical Systems Information Technologies
K974080	Critikon Soft Blood Pressure Cuff	Johnson & Johnson Medical, Inc.
Preamendent	Critikon Dura-Cuf®	Critikon Company, LLC
K991525	Sterile Neonatal Blood Pressure Cuff	Deroyal Industries, Inc.

Device Description:

The devices comprise tubing attached to an inelastic sleeve with an integrated inflatable bladder that is wrapped around the patient's limb and secured by hook-and-loop fastener. The devices tubing is connected to a non-invasive blood pressure measurement system with an extension hose.
The portfolio includes different standard sizes reusable and single-patient-use non-invasive blood pressure cuffs for adults, paediatrics, infants and single-patient-use NiBP-cuffs for neonates. Longer cuffs are marked with an additional range to which they can be safely used.

* NiBP: non-invasive blood pressure

Intended Use:

Dräger cuffs are intended to be used for automatic non-invasive blood pressure measurement.
Dräger cuffs are compatible with Dräger and Siemens patient monitors.
Neonatal cuffs are designed for single-patient use.

Conclusion:

The intended use and general construction as the predicate devices remain the same.
The NBP cuffs are identical in fit, form and function to marketed products named in the table above.
The cuffs are made of similar materials and colour coding is aligned to support clinical use.
Product labelling has been improved by measures to identify the correct size by arm circumference and arm length. It has been shown that product performance is given within the range the device can be used by clinicians.
The technological characteristics and the results of the performance data demonstrated that the NBP cuffs issued no new risks during design verification and validation which could question device use.
In accordance with the Federal Food and Cosmetic Act and 21 CFR Part 807, based on the information provided in this premarket notification Dräger Medical AG & Co. KG concludes that the NBP Cuffs are safe, effective and substantially equivalent to the predicate devices as described in this application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Draeger Medical AG&G Co., KG
c/o Ms. Joyce Kilroy
Draeger Medical System, Inc.
3135 Quarry Road
Telford, PA 18969

NOV 2 4 2009

Re: K092999
Trade/Device Name: NBP Cuff
Regulatory Number: 21 CFR 870.1120
Regulation Name: Blood pressure cuff
Regulatory Class: II (two)
Product Code: 74 DXQ
Dated: September 25, 2009
Received: September 28, 2009

Dear Ms. Kilroy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

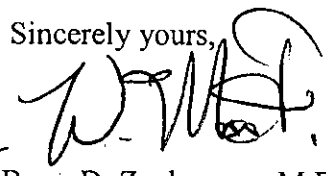
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known)	K 092999
Device Name	*NBP Cuff*
Indications for Use	Dräger cuffs are intended to be used for automatic non-invasive blood pressure measurement. Dräger cuffs are compatible with Dräger and Siemens patient monitors. Neonatal cuffs are designed for single-patient use.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use___X___ (Per 21 CFR 801. 109) OR Over-The-Counter Use_____

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092999